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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,201

05/15/2007

Jean-Pierre Sachetto

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ALEXANDRIA, VA 22314-1176

EXAMINER

HUGHES, ALICIA R

ART UNIT

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1614

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02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,201	Applicant(s) SACHETTO ET AL.	
	Examiner ALICIA R. HUGHES	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-10 and 13-22 are pending and the subject of this Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 13-22 (composition claims) are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 17 (composition claims) and 13-16 of U.S. Patent No. 5,792,795. The rejection stands for the reasons made of record in this office's actions of 28 January 2008 and 09 October 2008.

Applicants arguments are considered but allegations lacking sufficient factual support, and they do not take the place of objective evidence. It is well known in the art that Type A gelatin and Type B gelatin formation are both by the same process, the partial hydrolysis of collagenous material and regardless of their points of derivation, both Type A and Type B gelatins and blends thereof can be used to obtain a gelatin with the requisite viscosity and bloom strength. See U.S. Patent No. 4,935,243 (Col. 3, lines 20-46)[hereinafter referred to as "Borkan et al"].

Claim Rejection – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 13-22, 25, and 30-31 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,502,077 [hereinafter referred to as “Breivik et al”](the reference is being considered in its totality) in view of Borkan et al.

The teachings of Breivik et al Borkan et al from this Office’s Actions of 28 January 2008 and 09 October 2008, as well as the reasoning association therewith, are incorporated herein by reference in their entirety.

Applicants argue that there is no disclosure in Breivik et al of the use of any particular gelatin and most particularly, the use of Type A gelatin. Applicants further argue that the “reference speculates that the EPA and the DHA formulation could be in the form of the free acid. However such an embodiment is not exemplified” (Page 7 of Applicants' remarks of 25 November 2008). However, in the same paragraph that Applicants, by their own admission state “BREVIK exemplifies a soft gelatin capsule ...”! *Id.* Applicants go on further to say the “reference speculates that the EPA and the DHA formulation could be in the form of free acid.” *Id.* It is important to note that Breivik is an issued U.S. patent. Therefore, the disclosures therein are presumed valid and therefore, Applicants’ assertion that the “reference speculates” and arguments emanating therefore are but allegations lacking factual support.

Additionally, Applicants argue that by Borkan stating that gelatin may be of Type A, Type B or a mixture thereof that “BORKAN actually evidences the unexpected nature and nonobviousness of the claimed invention” (Page 7 of Applicants' remarks of 25 November 2008). This is unpersuasive, because as noted prior, Borkan et al teach that Type A gelatin and Type B gelatin formation are both by the same process, the partial hydrolysis of collagenous material and regardless of their points of derivation, both Type A and Type B gelatins and blends

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thereof can be used to obtain a gelatin with the requisite viscosity and bloom strength. (Col. 3, lines 20-46). Furthermore, gelatin types, between Type A and Type B are interchangeable and most often, plasticizers are added to produce soft gelatin that is chewable and the same has been known as early as the 1990s, based on the disclosures herein (Col. 3, lines 40-46). Applicant makes a claim, but provides no nexus. The mere statement that Borkan evidences the unexpected nature and nonobviousness of the claimed invention cannot be presupposed by teachings of two gelatin types only or mixtures thereof.

Applicants go on to state that one of skill in the art would lack motivation to combine and modify Breivik and Borkan to arrive at the instant invention stating in part as rationale that the primary difference between the different types is the manufacturing process. However, as noted by the Office pursuant to the teachings in Borkan et al, the formations are by the same processes and further, the use of the two types are known to be interchangeable.

Agreeably, the Examiner acknowledges the Patent Office's burden to consider objective indicia of nonobviousness when it is present and pursuant to Applicants' request, a more close review of Table 1 on page 10 was undertaken to ascertain whether indeed there were unexpected results. A review of the same did not reveal conclusive data to support the Applicants' claim of unexpected results, most especially in analyzing data with storage temperatures at 25 degrees and 30 degrees.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to conclude that the making and administration of a soft gelatin capsule containing EPA and DHA would be effective in the treatment of hypertriglyceridaemia.

Conclusion

No claims are currently in condition for allowance.

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614